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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/589,376

08/14/2006

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CU-5009 BWH

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EXAMINER

KOSAR, AARON J

ART UNIT

PAPER NUMBER

1651

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/589,376	<b>Applicant(s)</b> MIYAKE ET AL.	
	<b>Examiner</b> AARON J. KOSAR	<b>Art Unit</b> 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 14 August 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 7-11 and 13 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 7-11 and 13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>9/4/2008</u> .  | 6) <input type="checkbox"/> Other: _____                          |

### DETAILED ACTION

Applicant's amendment and argument filed December 24, 2008 in response to the non-final rejection, are acknowledged and have been fully considered. Any rejection and/or objection not specifically addressed is herein withdrawn.

Applicant has amended the claims by canceling claims 12 and 14 and amending claims 9-11. **Claims 7-11 and 13** are pending and have been examined on their merits.

#### ***Information Disclosure Statement (IDS)***

The information disclosure statement (IDS) submitted on September 4, 2008 has been considered by the Examiner; however, it is noted that the IDS contains references that are in a foreign language. The relevant portions of 37 CFR § 1.98 (a) and (b) state:

- (a) Any information disclosure statement filed under § 1.97 shall include the items listed in paragraphs (a)(1), (a)(2) and (a)(3) of this section...*
- (2) A legible copy of:*
- (i) Each foreign patent;*
  - (ii) Each publication or that portion which caused it to be listed, other than U.S. patents and U.S. patent application publications unless required by the Office;*
  - (iv) All other information or that portion which caused it to be listed.*
- (3)(i) A concise explanation of the relevance, as it is presently understood by the individual designated in § 1.56(c) most knowledgeable about the content of the information, of each patent, publication, or other information listed that is not in the English language. The concise explanation may be either separate from applicant's specification or incorporated therein.*
- (ii) A copy of the translation if a written English-language translation of a non-English-language document, or portion thereof, is within the possession, custody, or control of, or is readily available to any individual designated in § 1.56(c).*
- (b)(4) Each foreign patent or published foreign patent application listed in an information disclosure statement must be identified by the country or patent office which issued the patent or published the application, an appropriate document number, and the publication date indicated on the patent or published application.*
- (5) Each publication listed in an information disclosure statement must be identified by publisher, author (if any), title, relevant pages of the publication, date, and place of publication.*

Accordingly, the references have been considered to the extent presented in the English language; as presented and accompanied by reference document which is an English language equivalent or translation, to the extent cited in the instant Application's disclosure, or as cited by

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the Examiner in a PTO-892. References which have been considered have been initialed.

References which have not been considered or which are redundant have been lined through.

In the instant case the reference of SPARGO is redundant to the reference listed on the PTO-892 of 6/25/2008 and therefore has been lined through. Also the reference of MOTOROLA (JP 9-240125, 1997-09-16) has been corrected to address an inadvertent typographical error of the year.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

### ***Response to Arguments***

Applicant's arguments are acknowledged. Applicant has argued in general that the prior art does not teach the instant adhesion auxiliary portion of the instant claims and precludes cell-cell contact. Applicant's arguments have been fully considered, but respectfully, they are found to be not persuasive, for the reasons of record and as follows.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that Singhvi teaches that a portion of the cells "are allowed to form bridges across the cytophobic regions and contact each other" (Singhvi, abstract). Additionally, the features upon which applicant relies (i.e., a cell; cells which *are* bound to each other) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

**Claims 7 and 8** remain rejected under 35 U.S.C. 102(b) as being anticipated by SINGHVI (US 6,368,838 B1, of record) or SPARGO (U:PTO:892 of record) or KOICHI (PTO-1449: JP 2003-009870, of record).

The claims are generally drawn to a substrate comprising a base material, and a cell adhesion portion, and a cell auxiliary portion inhibiting cell adhesion.

SINGVHI teaches a substrate comprising a baseplate or substrate and a plurality of cytophilic/biophilic islands isolated by cytophobic/biophilic regions (e.g abstract; figure 1). Singhvi also teaches an array grid formed from a linear template, including an electron microscopy grid or parallel lines (column 22, examples 1 and 3).

SPARGO teaches a glass substrate having a linear, alternating domain deposition pattern and the use of photolithography to provide a substrate for differential adherence and growth of cells. Spargo also teaches culturing of endothelial cells, including human umbilical vein endothelial (HUVE) cells (e.g. ¶2, page 11071, right column; figure 3).

KOICHI teaches a compartmentalized or fine-structure substrate comprising cell-adhesive and cell-non-adhesive areas based on hydrophobicity/hydrophilicity of graft layers comprising the substrate composition (English abstract).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

*This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).*

### ***Response to Arguments***

Applicant has argued that the compositions of the claims and prior art differ in that the prior art structure is incapable of providing an excellent arrangement of cells when the cell culture region is large, and that Singhvi teaches preventing cell-cell contact. Applicant's arguments have been fully considered but they are not persuasive.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., a large cell culture area, a cell, preferred attachments of cells, a preferred assignment of a specific plane by which a planar view is referenced) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

In response to applicant's argument of an intended use (e.g. to provide an arrangement of cells which is excellent, cell-cell binding), a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Whereas Singhvi - though teaching select preferred embodiments where cell-cell contact *can be* prevented - by teaching that the composition *is also capable of providing cell-cell contact*, teaching “cytophobic islands can be wide enough that less than 10 percent of the cells...*are allowed to form bridges across the cytophobic regions and contact each other*” (Abstract, emphasis added), the structure of Singhvi still meets the claims.

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Patents are relevant as prior art for all they contain. "The use of patents as references is not limited to what the patentees describe as their own inventions or to the problems with which they are concerned. They are part of the literature of the art, relevant for all they contain." *In re Heck*, 699 F.2d 1331, 1332-33, 216 USPQ 1038, 1039 (Fed. Cir. 1983). A reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill the art, including nonpreferred embodiments. *Merck & Co. v. Biocraft Laboratories*, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989). Nonpreferred embodiments constitute prior art. Disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. *In re Susi*, 440 F.2d 442, 169 USPQ 423 (CCPA 1971). "A known or obvious composition does not become patentable simply because it has been described as somewhat inferior to some other product for the same use." *In re Gurley*, 27 F.3d 551, 554, 31 USPQ2d 1130, 1132 (Fed. Cir. 1994). See M.P.E.P. § 2123.

Additionally to the extent Applicant has, in part, provided select arguments unsupported by the objective evidence of record, the arguments are not persuasive. The arguments of Counsel cannot take the place of evidence in the record. *In re Schulze*, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965).

**Claims 7-11 and 13** are/remain rejected as obvious over SINGHVI (US 6,368,838 B1, of record).

The claims are interpreted as discussed on the record. Additionally, the claims are drawn to a patterned substrate having an inter/intra concave:convex distances of 0.5-30 micrometers.

While SINGHVI, for the reasons of record, teaches a substrate, to the extent that Singhvi may be silent with respect to a particular shape, dimension, or pattern of the cell-binding and cell-nonbinding regions, it would have been obvious to provide a substrate having the features of: 0.5-30 micrometer distances, concavoconvex shapes, and/or linear arrangements. It would have been obvious to have provided a plate/substrate having the features of 0.5-30 micrometer distances, concavoconvex shapes, and/or linear arrangements (herein referred to collectively as “the preferred features”), because Singhvi teaches manipulations of the morphology of the patterned plate.

One would have been motivated to modify the plate to have the preferred features, because Singhvi teaches configurations and methods of modifying the configurations, including: (1) adjusting to vary the island size relative to the desired cell dimensions, including teaching of 20 micrometer white blood cells and 1 micrometer *Xenopus* oocytes (column 12, ¶3-4); (2) adjusting an island area or shape, including “any size or shape, including rectilinear, circular, ovoid, and arbitrary shapes” (column 11, ¶ 3, emphasis added); and arranging in [linear] arrays, including grids wherein “irrespective of the shape of the islands, a pattern consisting of an array of islands is referred to as a grid” or parallel lines (column 11, ¶ 3-4; figure 1).

One would have had a reasonable expectation of success in making the composition having the preferred features, because the alteration of a micro array for cell adhesion and the modes of manipulation thereof are taught by Singhvi and the selection and optimization of a particular arrangement would be well within the purview of the skilled artisan.

Additionally, Singhvi is relied upon for the reasons discussed above. If not expressly taught by Singhvi, based upon the overall beneficial teaching and methods provided by this



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reference with respect shapes, sizes, and arrangements of the islands in the manner disclosed therein, including the teachings of using shapes with curvature (concave or convex, e.g. patterning with circular and ovoid shapes) and providing instruction on tailoring islands and spacer regions to a cell morphology, the selection of a particular shape and arrangement of islands and spacer regions is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

Patents are relevant as prior art for all they contain. "The use of patents as references is not limited to what the patentees describe as their own inventions or to the problems with which they are concerned. They are part of the literature of the art, relevant for all they contain." *In re Heck*, 699 F.2d 1331, 1332-33, 216 USPQ 1038, 1039 (Fed. Cir. 1983). A reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill the art, including nonpreferred embodiments. *Merck & Co. v. Biocraft Laboratories*, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989). Nonpreferred embodiments constitute prior art. Disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. *In re Susi*, 440 F.2d 442, 169 USPQ 423 (CCPA 1971). "A known or obvious composition does not become patentable simply because it has been described as somewhat inferior to some other product for the same use." *In re Gurley*, 27 F.3d 551, 554, 31 USPQ2d 1130, 1132 (Fed. Cir. 1994). See M.P.E.P. § 2123.

In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the

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invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AARON J. KOSAR whose telephone number is (571)270-3054. The examiner can normally be reached on Monday-Thursday, 7:30AM-5:00PM, ALT. Friday,EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Aaron J Kosar/  
Examiner, Art Unit 1651

/Lora E Barnhart/  
Primary Examiner, Art Unit 1651